

Patent  
Case No. HA688a

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: 1611  
Examiner: M. Berch  
Applicant: Jeffrey A. Robl  
Serial No.: 08/833,172  
Filed: April 4, 1997  
For: N-FORMYL HYDROXYLAMINE CONTAINING COMPOUNDS  
USEFUL AS ACE INHIBITORS AND/OR NEP INHIBITORS

Princeton, New Jersey 08543-4000  
April 20, 2000

REPLY BRIEF

To the Assistant Commissioner for Patents:

This is in reply to the Examiner's Answer mailed March 29, 2000, which is in response to Appellant's Brief on Appeal filed June 14, 1999, in connection with the subject application.

The Examiner rightfully points out that the brief does not contain statements identifying the (1) Real Party in Interest and (2) Related Appeals and Interferences. It is respectfully requested that the following serve to incorporate the Real Party in Interest and Related Appeals and Interferences in the Appeal Brief.

"The Real Party in Interest

The Real Party in Interest is Bristol-Myers Squibb Company as evidenced by the Assignment recorded on April 4, 1997, Reel/Frame: 8526/0522 (copy of which is enclosed herewith)."

"Related Appeals and Interferences

There are no Appeals and/or Interferences relating to the instant Appeal."

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Please advise if Appellant is required to submit a new Appeal Brief to incorporate statements regarding "The Real Party in Interest" and "Related Appeals and Interferences."

With regard to "Issue 1" raised in the Examiner's Answer, the Examiner points out that "there is a missing left parenthesis in claim 1, at the end of the definition for R<sup>6</sup>."

Enclosed herewith is a "Third Amendment After Final Rejection" wherein the missing left parenthesis in Claim 1 at the end of the definition for R<sup>6</sup> has been added. In addition, a left parenthesis at the end of the definition of R<sup>7</sup>, R<sup>8</sup> and R<sup>9</sup> has been added as well.

It is believed that amending Claim 1 to include the left parenthesis at the end of the definition for R<sup>6</sup> (and R<sup>7</sup>) removes "Issue 1" from this Appeal.

With respect to "Issue 2", the Examiner maintains that "the term 'cycloheteroalkyl' is indefinite. It has no standard meaning, and is internally inconsistent."

The Examiner acknowledges the "numerous references" submitted by Appellant "in an effort to establish that the term has a standard meaning...."

The Examiner maintains that cycloheteroalkyl may have a number of meanings and states that

"a cycloalkyl cannot have a heteroatom in the ring, because it would then no longer be a cycloalkyl. It could have a heteroatom as a substituent... or it could mean an alkyl substituted by a cycle with a heteroatom in it, i.e. (heterocyclo)alkyl."

In the Appeal Brief, Appellant states that "cycloheteroalkyl is a saturated ring which includes at least one heteroatom." By the above statement, Appellant is responding to the Examiner's statement that "the term

'cycloheteroalkyl' is indefinite since a cycloalkyl cannot have a heteroatom." Appellant agrees that cycloalkyl cannot have a heteroatom. However, it is implicit in the term "cycloheteroalkyl" that the ring system referred to as "cyclo" includes at least the heteroatom. Appellant submitted 9 patents to establish that the term "cycloheteroalkyl" is known to those having ordinary skill in the art. Appellant maintains that these references establish the definition of "cycloheteroalkyl" and the term as employed herein is to be interpreted in light of the definition in 7 of the submitted references which are enumerated on page 6 and 7 of the Appeal Brief.

In U.S. Patent No. 5,332,728 and 5,488,068 claims including the term "cycloheteroalkyl" were allowed and issued even though no definition was given for this term. This sets a precedent for use of the term in the claims without including a definition in the specification.

The definition of "cycloheteroalkyl" in all of the other 7 references all include the following:

"The term 'cycloheteroalkyl' as used herein... refers to a 5-, 6- or 7-membered saturated ring which includes 1 to 2 hetero atoms such as nitrogen, oxygen and/or sulfur...."

This is what one of ordinary skill in the art would reasonably believe to be the definition of "cycloheteroalkyl" as employed herein. These 7 references provide basis for the meaning of this term. There can be no other interpretation or meaning of this term as imparted by these references.

The linkage or place of bonding mentioned in the references is irrelevant.

Appellant is not asserting that the term "cycloheteroalkyl" as employed herein should be interpreted differently than as set out in the above mentioned references.

The fact that all of the references submitted are assigned to E.R. Squibb & Sons, Inc. or Bristol-Myers is of no consequence. The references establish a definition for "cycloheteroalkyl" for one skilled in the art. Those skilled in the art from Bristol-Myers Squibb or other companies may employ the term "cycloheteroalkyl" knowing its definition has been previously established as discussed above.

In view of the foregoing, it is submitted that Claim 1 which employs the term "cycloheteroalkyl" is in compliance with 35 USC § 112, second paragraph with regard to use of such term.

With regard to "Issue 3", the Examiner contends that the definition of R is unclear. The first part of the definition for R defines R as H, alkyl, alkenyl, aryl-(CH<sub>2</sub>)<sub>p</sub>-, heteroaryl-(CH<sub>2</sub>)<sub>p</sub>- or cycloheteroalkyl-(CH<sub>2</sub>)<sub>p</sub>-. It is the second part of the definition with which the Examiner has a problem, namely, "R can be joined together with the carbon to which it is attached to form a 3 to 7 membered ring...."

The remainder of the definition, namely "which may be optionally fused to a benzene ring" is of no relevance here.

The Examiner maintains that "R is joined to a Carbon via a single valence and that a monovalent group cannot form a ring with that Carbon."

Appellant's structural formula as claimed shows R is bonded to a carbon. However, Appellant in Claim 1 defines R so that it can be joined together with the Carbon (to which it is attached) to form a 3- to 7-membered ring. Appellant has not limited R to a monovalent group. It certainly may be

monovalent, but it may also be bivalent or else it could not form the ring with the Carbon (and Appellant claims that R forms a ring with the Carbon)..

The Examiner questions the nature of the 3-7-membered ring. The ring must be formed with R and the Carbon to form a ring with 3-7 members. The definition of R is H, alkyl, alkenyl, aryl-(CH<sub>2</sub>)<sub>p</sub>-, heteroaryl-(CH<sub>2</sub>)<sub>p</sub>- (p may be 0) or cycloheteroalkyl-(CH<sub>2</sub>)<sub>p</sub>- (p may be 0). Where one refers to a 3-7-membered ring, it is implicit that the ring is a monocyclic ring unless indicated otherwise. The ring thus can be formed with any of the R groups which will give a 3 to 7-membered ring. In such case, R cannot be aryl, heteroaryl or cycloheteroalkyl since if R included any of these to form a 3-7 membered ring, a bicyclic ring would be formed. Accordingly, this leaves only alkyl or alkenyl as R which will, in fact, form a 3 to 7-membered carbocyclic monocyclic ring.

Appellant is interpreting Claim 1 as would anyone skilled in the art. Appellant is not reading anything into Claim 1 which is not inherent therein or apparent to one skilled in the art. It is Appellant's intention that R can be taken with the Carbon to form a 3-7 membered ring which inherently is monocyclic and thus must be carbocyclic (since R can only be alkyl or alkenyl if a monocyclic ring is to be formed).

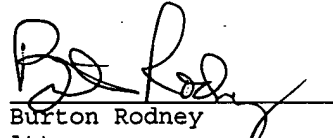
In view of the above, it is submitted that the definition of R is complete and Claim 1 clearly is in compliance with 35 USC § 112, second paragraph. In addition, Claims 6, 7, and 12 to 14, which depend from Claim 1 are therefore in compliance with 35 USC § 112, second paragraph.

CONCLUSIONS

It is submitted that in view of the aforementioned arguments, Claims 1, 6, 7, and 12 to 14 clearly comply with 35 USC § 112, second paragraph.

Therefore, it is believed that the Examiner's final rejection of the claims on appeal (Claims 1, 6, 7, and 12 to 14) should be reversed and that such claims should be allowed.


Respectfully submitted,

  
Burton Rodney  
Attorney

Date: April 20, 2000

BR:mz  
(609) 252-4336

I hereby certify that this correspondence is being deposited with the United States postal service as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents, Washington, D.C. 20231, on April 20, 2000

  
Burton Rodney  
Attorney

Date: April 20, 2000